UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ROBERT GUSTAVSEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE on behalf of themselves and all others similarly situated, Plaintiffs, v. ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.; FALCON PHARMACEUTICALS, Ltd.; SANDOZ, INC.; ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; PFIZER INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; BAUSCH AND LOMB INCORPORATED; ATON PHARMA, INC.; MERCK & CO., INC.; MERCK, SHARP & DOHME CORP., PRASCO, LLC, and . AKORN, INC. Defendants.	)	Civil Action No. _____ Class Action

CLASS ACTION COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

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The plaintiffs, ROBERT GUSTAVSEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE ("Plaintiffs"), on behalf of themselves and all members of the putative Classes set forth below, and for their Complaint against Defendants Alcon Laboratories, Inc.; Alcon Research, Ltd.; Falcon Pharmaceuticals, Ltd.; Sandoz, Inc.;[1] Allergan, Inc.; Allergan USA, Inc.; Allergan Sales, LLC.;[2] Pfizer Inc. ("Pfizer"); Valeant Pharmaceuticals International, Inc. ("Valeant"); Bausch and Lomb Incorporated ("B+L"); Aton Pharma, Inc. ("Aton");[3] Merck & Co., Inc.; Merck, Sharp & Dohme Corp.[4]; Prasco, LLC ("Prasco) and Akorn, Inc. ("Akorn") (collectively "Defendants"), allege as follows based on personal knowledge as to their own actions and on information and belief as to Defendants' conduct and practices:

INTRODUCTION

1. Plaintiffs bring this class action individually and on behalf of Classes of persons and entities (referred to herein collectively as "Class Members," or "Classes") who or which have paid all or part of the purchase prices of prescription eye drops manufactured and sold by Defendants and who or which were compelled by Defendants' unfair and illegal practices to pay for much more medication than the users of those medications needed.

2. Prescription eye drops, also known as "topical ophthalmic pharmaceuticals," constitute a multi-billion dollar industry in the United States. Millions of Americans, including Plaintiffs and many other consumers, take these expensive medications pursuant to doctors'

[1] Alcon Laboratories, Inc.; Alcon Research, Ltd.: Falcon Pharmaceuticals, Ltd.; and Sandoz, Inc. are collectively referred to herein as "Alcon."

[2] Allergan, Inc.; Allergan USA, Inc.; and Allergan Sales, LLC. are collectively referred to herein as "Allergan."

[3] Valeant, B+L, and Aton are collectively referred to as "Valeant Defendants."

[4] Merck, Sharpe & Dohme Corp. and Merck & Co., Inc., are collectively referred to herein as "Merck."

prescriptions for serious diseases and conditions such as glaucoma, allergies, infections, inflammations, pre- and post-operative conditions, and others.

3. These patients are entitled to receive the full use and therapeutic benefit of the entire product they purchase. Yet because of the Defendants' illegal schemes to increase their profits at consumers' expense, patients are compelled to purchase larger quantities that, through no fault of their own, go to waste, and as a result they and their third-party payors pay much more than they should for the treatment they need.

4. Defendants sell their prescription eye drop products as fluid in plastic bottles. They sell a given volume of medication (*e.g.*, 2.5 or 5.0 mL) for a certain price, without stating how many doses are contained in the bottles or how many days they will last.

5. A wealth of scientific literature spanning the past several decades establishes that these bottles, which also serve as dispensers, emit drops so large that they exceed the capacity of the fornix, the area between the eye and the lower eyelid. As a result, and as that literature likewise shows, much or most of the medication runs down the patient's cheeks, where it can cause allergy or pigmentation, or drains into their nasolacrimal drainage systems and from there into the bloodstream where it can create a risk of toxic side effects. By Defendants' design, the excess product cannot be used, is entirely wasted, provides no pharmaceutical benefit, and is often harmful.

6. Much of this literature was published or supported by these Defendants. For example, twenty years ago, scientists from Defendant Alcon Laboratories, Inc., joined with scientists from Johns Hopkins School of Medicine in a double-blind study using dropper tips that emitted drops of only 16 μL (microliters, or a millionth of a liter). They found those drops to have the same therapeutic benefit as 30 μL drops but were better tolerated, and they published

the results in a peer-reviewed paper in the American Journal of Ophthalmology.[5] Yet Alcon has never sold prescription eye drops that are as small as 16 μL.

7. In a scientific article published in the peer-reviewed Journal of Ocular Pharmacology and Therapeutics in 2006, scientists from Defendant Allergan, Inc., along with co-authors from the University of Chicago, set forth in three sentences the factual and scientific basis for this lawsuit:

> Studies have shown that the bioavailability and efficacy of drops as small as 15 μL are equivalent to those of larger drops. Therefore, smaller drops would be preferable to minimize systemic exposure and spilled or wasted medication. Obviously, a smaller drop size would mean that more doses could be dispensed from each bottle of medication, providing cost savings to patients and managed care providers.[6]

8. Again in 2011, one of these Allergan scientists, writing in the medical e-book *Glaucoma – Current Clinical and Research Aspects*, reaffirmed those principles: "Smaller size drops on the order of 15 μL, have an efficacy and bioavailability equivalent to larger drops, without the waste. In fact, drops of this size are preferable, as they minimize systemic exposure and wastage."[7]

9. Yet Defendants' eye drops are uniformly much larger than 15 μL. Some are more than three times that size.

10. There is no legitimate reason why Defendants have not supplied smaller eye drops. As they have long known, the size of the drop is determined by a factor under their control, the dimensions of the plastic dropper tip. More than a quarter century ago, eye doctors

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[5] Mark J. Vocci et al., *Reformulation and Drop Size of Apraclonidine Hydrochloride*, 113 Am. J. Ophthalmology 154, 160 (1992)

[6] Richard Fiscella *et al.*, *Efficiency of Instillation Methods for Prostaglandin Medications*, 22 J. Ocular Pharmacology and Therapeutics 477, 478 (2006).

[7] J. Walt and F. Alexander, "*Drops, Drops, and More Drops*," in Glaucoma – Current Clinical and Research Aspects, (P. Gunvant ed. 2011) at 208.

created dropper tips in the laboratory that emitted drops of 11 and 19 µL and published the tip dimensions in the American Journal of Ophthalmology, a peer-reviewed scientific journal.[8]

11. Yet Defendants have persisted in their unfair, unethical, unconscionable, and unlawful practices of selling prescription ophthalmic medicine in dispensers that emit much larger eye drops. As a result, consumers use more medication than they should, run out of medicine before they should, and have to buy additional bottles at great expense, providing increased, but unfair, unethical and unconscionable profits for Defendants.

12. What makes the actions of Defendants even worse is the seriousness of the diseases that their medications treat. For example, glaucoma, which is caused by an increased pressure inside the eye, is the leading cause of blindness in blacks and Hispanics and the second-leading cause in whites. It disproportionately affects the elderly on fixed incomes. Some of the consequences of glaucoma include the inability to drive, recognize faces, walk, maintain balance, and read. According to Allergan, it afflicts more than a million-and-a-half Americans. The only successful therapy for glaucoma is to lower the eye's pressure. Other than prescription eye drops, there is no commercially available medication to accomplish this outcome and no commercially available delivery device for this medication other than the eye drop dispensers in which these medications are sold. Once diagnosed with the disease, patients need to take their eye drops every day for the rest of their lives at an annual cost of many hundreds or even thousands of dollars.

13. Moreover, the excess portion of the drops that drains through the lacrimal duct ultimately enters the bloodstream without first undergoing metabolic inactivation in the liver.

[8]Brown, Reay H. et al., *Creating Smaller Eyedrops by Reducing Eyedropper Tip Dimensions*, 99 Am. J. Ophthalmology 460-464 (1985).

This can lead to a risk of side effects such as decreased cardiovascular response to exercise, lowered blood pressure and emotional or psychiatric effects.

14. In addition, the size of the drops is so large that it can lead to an additional health risk for these patients by contributing to a situation in which they run out of their medication before their insurer or other third-party payor will reimburse them for a replacement bottle. Because these drugs are so expensive, many patients cannot afford to buy the drugs without reimbursement from their third-party payor and, therefore, go without, placing them at increased risk of loss of vision or complete blindness.

15. It is manifestly unfair for Defendants to sell products that are sold in a way that compels consumers to buy unneeded amounts and that thereby also creates a risk of harm. Both aspects – the forced purchase of unneeded amounts and the creation of unwarranted health and safety risks – render Defendants' practices unfair under the policy of the Federal Trade Commission, which has been incorporated into the Massachusetts Consumer Protection Act, (M.G.L. c. 93A, § 1 et seq) and similar statutes.

16. For all these reasons, Defendants' practices of selling topical prescription ophthalmic pharmaceuticals are unfair, unethical and unconscionable, violate the Massachusetts Consumer Protection Act, and similar statutes of other states and give rise to liability pursuant to the common law of the states enumerated below.

17. Plaintiffs bring this lawsuit on behalf of themselves and proposed Classes of similarly situated consumers and third-party payors who paid all or part of the purchase price of multi-dose bottles of prescription eye drops manufactured by Defendants. Plaintiffs seek to redress Defendants' illegal conduct and to recover as damages the excessive costs for inherently wasted medication manufactured and sold by Defendants, as well as punitive damages.

THE PARTIES

Massachusetts Plaintiffs

18. Plaintiff Robert Gustavsen is a resident of Braintree, Massachusetts. Mr. Gustavsen purchased and used prescription eye drops manufactured and sold by Alcon during the four years preceding the filing of this lawsuit.

19. Plaintiff Joseph Cugini is a resident of Weymouth, Massachusetts. Mr. Cugini purchased and used prescription eye drops manufactured and sold by Allergan during the four years preceding the filing of this lawsuit**.**

20. Plaintiff Demetra Cohen is a resident of Newburyport, Massachusetts. Ms. Cohen purchased and used prescription eye drops manufactured and sold by Pfizer during during the four years preceding the filing of this lawsuit**.**

New York Plaintiffs

21. Plaintiff Lee Wilburn is a resident of Rochester, New York. Mr. Wilburn purchased and used prescription eye drops manufactured and sold by Alcon, Akorn and Pfizer Defendants during the four years preceding the filing of this lawsuit**.**

22. Plaintiff Jackie Corbin is a resident of Roosevelt, New York. Mr. Corbin purchased and used prescription eye drops manufactured and sold by Allergan, Pfizer, Merck, Prasco and Valeant Defendants during the four years preceding the filing of this lawsuit**.**

23. Plaintiff Mary Law is a resident of Bronx, New York. Ms. Law purchased and used prescription eye drops manufactured and sold by Alcon during the four years preceding the filing of this lawsuit**.**

24. Plaintiff Cecelia Brathwaite is a resident of Brooklyn, New York. Ms. Brathwaite purchased and used prescription eye drops manufactured and sold by Allergan and Merck Defendants during the four years preceding the filing of this lawsuit**.**

The Alcon Defendants

25. Three of the Alcon Defendants, Alcon Laboratories, Inc.; Alcon Research, Ltd.; and Falcon Pharmaceuticals, Ltd., are corporations incorporated under the laws of Delaware with their principal place of business at 6201 S. Freeway, Fort Worth, TX 76134. The fourth, Sandoz, Inc., is a corporation incorporated under the laws of Delaware with its principal place of business at 59 Route 10, East Hanover, N.J. 07936.

26. Defendant Alcon Laboratories, Inc. performs selling, marketing and distribution activities in the United States for Alcon's prescription eye drop products. Defendant Alcon Research, Ltd., is responsible for Alcon's U.S. manufacturing and research and development operations for Alcon's prescription eye drop products. Falcon Pharmaceuticals, Ltd., manufactures and, until on or about April 2011, marketed and sold Alcon's generic ophthalmic products in the United States. Since on or about April 2011, Sandoz Inc. has marketed and sold Alcon's generic ophthalmic products in the United States.

27. The following table lists Alcon's principal topical ophthalmic pharmaceutical products sold in multi-dose containers during the applicable class periods:

Glaucoma	**Ocular Anti-Infectives/ Anti-Inflammatories**	**Ocular Allergy**	**Generics**
Travatan	*Vigamox*	*Patanol*	Timolol
Travatan Z	*Moxeza*	*Pataday*	Timolol GFS
Azopt	*Nevanac*		Betaxolol
Betoptic	*TobraDex*		Carteolol
Betoptic S	*TobraDex ST*		Apraclonidine
Simbrinza	*Maxitrol*		Latanoprost
Iopidine	*Durezol*		Levobunolol
			Metipranolol
			Pilocarpine
			Prednisolone Acetate
			Dorzolamide
			Dorzolamide/Timolol
			Ciprofloxacin
			Brimonidine Tartrate
			Trifluridine
			Tobramycin/ Dexamethasone

The Allergan Defendants

28. Two of the Allergan Defendants, Allergan, Inc. and Allergan USA, Inc., are corporations incorporated under the laws of Delaware with their principal place of business at 2525 Dupont Drive, Irvine, California 92612. The third, Allergan Sales, LLC, is a California limited liability corporation with its principal place of business at the same address.

29. During the applicable class periods, Allergan manufactured and sold prescription eye drop products in multi-dose containers as listed below for the following conditions:

A. **Glaucoma.** Lumigan, Alphagan, Alphagan P, Combigan, and Betagan.

B. **Allergy.** Acular, Alocril, Elestat and Lastacaft.

C. **Inflammation.** Acular LS and Pred Forte.

D. **Infection.** Zymar and Zymaxid.

Pfizer

30. Pfizer is a corporation incorporated under the laws of Delaware with its principal place of business at 225 E. 42nd Street, New York, NY 10017.

31. Pfizer's principal prescription eye drop product sold in multi-dose containers is the glaucoma drug Xalatan. Until Xalatan lost its exclusivity in March 2011, it was the largest selling prescription eye drop in the United States and is still widely sold.

The Valeant Defendants

32. Valeant is a corporation organized under the laws of Canada, with its principal place of business at 4787 Levy Street, Montreal, Quebec, Canada H4R 2P9. Its U.S. Headquarters are at 700 Route 202/206, Bridgewater, NJ 08807.

33. B+L is a corporation incorporated under the laws of New York with its principal place of business at Bausch & Lomb Place, Rochester NY 14604. On August 5, 2013, Valeant completed its acquisition of B+L. According to information on Valeant's web site, "Valeant's

existing ophthalmology businesses have been integrated into the Bausch + Lomb division to create a global eye health platform."[9] In or about July 2013, Valeant announced that it was moving B+L's principal place of business to Bridgewater, NJ.

34. Aton Pharma, Inc., is a corporation incorporated under the laws of Delaware with its principal place of business located in Lawrenceville, New Jersey. Valeant completed its acquisition of Aton on May 27, 2010.

35. The prescription eye drops of Valeant's B+L unit that are sold in multi-dose containers include Besivance (an anti-bacterial); Optipranolol, Brimonidine, Dorzolamide, Timolol Maleate and Levobunolol (glaucoma); Lotemax and Zylet (steroid anti-inflammatories) and Alrex (allergy). In or about June 2012, B+L acquired and succeeded to Ista Pharmaceuticals, Inc. ("Ista"), which had manufactured and sold prescription eye drops Xibrom and Bromday (anti-inflammatory), Bepreve (for allergic conjunctivitis) and Istalol (glaucoma), and began manufacturing and selling those products. Prior to that time, B+L had manufactured those products under contract with Ista.

36. On February 25, 2009, Aton acquired the U.S. marketing rights to Timoptic and Timoptic-XE, two glaucoma drugs sold in multi-use eye drop dispensers. Aton has sold those drugs in the United States since that time.

The Merck Defendants

37. The Merck Defendants are corporations incorporated under the laws of New Jersey and have their principal places of business at One Merck Drive, Whitehouse Station, N.J. 08889.

[9] http://www.valeant.com/about/acquisition-faqs (accessed December 5, 2013).

38. One of the Merck Defendants, Merck, Sharpe & Dohme Corp., is a wholly-owned subsidiary of the other, Defendant Merck & Co, Inc. Merck, Sharpe & Dohme, Inc. was formerly known as Merck & Co., Inc. On or about November 4, 2009, Merck & Co., Inc. merged with Schering-Plough Corporation. As a result of the merger, Schering-Plough Corporation acquired all of the shares of Merck & Co., Inc., and renamed itself Merck & Co., Inc.

39. Among other products, Merck's prescription eye drop products in multi-dose containers include the glaucoma drugs Cosopt and Trusopt and the anti-bacterial Azasite. Beginning in or about October 2008, Merck manufactured generic versions of Cosopt and Trusopt for Prasco. In addition, until it sold its Timoptic brand in February 2009, Merck manufactured and sold the glaucoma drugs Timoptic and Timoptic-XE.

Prasco

40. Prasco, LLC ("Prasco"), is a limited liability company formed under the laws of the State of Ohio, with its principal place of business at 6125 Commerce Court, Mason, OH 45040.

41. Prasco distributes "Authorized Generic" pharmaceutical products that are 100% identical to their brand-name equivalents because they are manufactured by the brand-name company and simply made available as a generic under private label. They are the brand-name drug, just packaged under the Prasco private label name.

42. Among the Authorized Generic pharmaceutical products that Prasco distributes are two products manufactured for it by Merck: Dorzolamide Hydrochloride/Timolol Maleate Ophthalmic Solution, which is identical to Merck's Cosopt; and Dorzolamide Hydrochloride Ophthalmic Solution, which is identical to Merck's Trusopt. Prasco distributes these products in

the same Merck dispensing container, known as Ocumeter Plus, as the one in which Cosopt and Trusopt are sold.

Akorn

43. Akorn is a corporation incorporated under the laws of Louisiana and has its principal place of business at 1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045.

44. Akorn manufactures a full line of therapeutic ophthalmic pharmaceuticals, along with other pharmaceuticals. Its therapeutic ophthalmic products include antibiotics, steroids, steroid combinations, glaucoma medications, decongestants/antihistamines and anti-edema medications. Among its ophthalmic products sold in eye drop form are Timolol Maleate, Apraclonidine, Betaxolol, Brimonidine, and Latanoprost.

JURISDICTION AND VENUE

45. This is a class action filed under Rule 23 of the Federal Rules of Civil Procedure.

46. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d), which under the provisions of the Class Action Fairness Act explicitly provides for the original jurisdiction in the federal courts of any class action in which any member of the Plaintiff class is a citizen of a State different from any Defendant, and in which the matter in controversy exceeds the aggregate sum of $5,000,000, exclusive of interest and costs, unless the number of members of all proposed Plaintiff classes in the aggregate is less than 100.

47. Plaintiffs are citizens of Massachusetts and New York. Defendants are citizens of various states, as set forth above. Therefore, diversity of citizenship exists pursuant to 28 U.S.C. § 1332(d)(2)(A).

48. The total claims of the individual Class Members are in excess of $5,000,000 in the aggregate, exclusive of interest and costs.

49. The number of members of the Plaintiff Classes is at least 100.

50. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

JURY DEMAND

51. For each of the Counts in this Complaint, Plaintiffs demand a jury trial regarding each of the issues to the extent it is allowed by law.

FACTUAL ALLEGATIONS REGARDING DEFENDANTS' LIABILITY

52. Plaintiffs' claims are simple: For many years, each Defendant has separately engaged in an unfair, unscrupulous, and unconscionable scheme, in violation of the Massachusetts Consumer Protection Act and the consumer protection statutes of other states, to increase its profits by selling prescription eye drops in a form that compels consumers to buy and spend money for expensive medication that inherently goes to waste. Specifically, Defendants sell these drugs in dispensers that emit drops that are so large that they exceed the capacity of the eye, with large portions being expelled from the eye and providing no benefit and a risk of harm. As a result, Plaintiffs and other Class Members have been compelled to pay for more of Defendants' medication than they should have, allowing the Defendants to unjustly and inequitably retain the excess funds paid by the Plaintiffs and other Class Members .

53. The scientific principles that underlie this claim have been recognized in peer-reviewed medical and pharmaceutical literature over the past four decades, including literature published by, and financially supported by, some of these very Defendants. This Complaint describes that literature.

The Amount of Medication That the Eye Can Absorb Is Limited by the Eye's Capacity

54. The literature establishes, among other scientific principles, that the volume of the inferior fornix, located in the conjunctival cul-de-sac, is only 7-10 microliters ("μL") under normal conditions. When a large eye drop is added to that volume, it leads to overflow because

"[t]he conjunctival sac can only hold momentarily about 20-30 µL of fluid without overflow onto the cheek."[10] None of that overflow enters the inner eye, which is the site of action of the drug.

55. These principles have been known for decades. Physicians with the University of Missouri-Kansas City wrote in the American Journal of Ophthalmology during the 1980s:

> Under normal conditions, the human tear volume is approximately 7 µl. This is divided into the upper and lower marginal tear menisci (3 µL per meniscus for a total of 6 µL) and 1 µL in the precorneal tear film. The eye can hold about 30 µl without overflow if great care is exercised and the subject is not allowed to blink. In the clinical situation, eyedrop administration is followed by reflex blinking, with most of the eyedrop lost to drainage in the first 15 to 30 seconds. Thus, the greatest portion of an administered eye drop is not used for the desired pharmacologic effect.[11]

56. In a major review paper nearly a decade ago, two scientists from the University of Antwerp Laboratory of Pharmaceutical Testing and Biopharmacy concurred with the above principles:

> Normally, the human tear volume in the palpebral fissure averages 7 µl in the upright position, with 1 µl in the precorneal tear film and about 3 µl in each marginal tear meniscus. The maximum volume that the palpebral fissure can contain without overflowing is estimated at 30 µl under normal conditions when the patient is upright and not blinking. Sudden increases of volume, such as those created by the instillation of eye drops, are diminished rapidly by reflex blinking and tearing and increased rates of drainage. Restoration of the normal tear volume requires about two to three minutes with most of the excess volume lost to overflow and drainage in the first 15-30 seconds. The larger the volume instilled, the more rapidly it is drained through the naso-lacrimal duct system. [12]

57. More recently, scientists from Emory University Eye Center wrote in the Journal of Glaucoma:

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[10] Luc Van Santvliet and Annick Ludwig, *The Influence of Penetration Enhancers on the Volume Instilled of Eye Drops*, 45 Eur. J. Pharmaceutics and Biopharmaceutics 189, 190 (1998).

[11] Charles M. Lederer & Ralph E. Harold, *Drop Size of Commercial Eye Glaucoma Medications*, 101 Am. J. Ophthalmology 691, 694 (1986) (footnote omitted).

[12] Luc Van Santvliet & Annick Ludwig, *Determinants of Eye Drop Size*, 49 Surv. Ophthalmology 197-213 at 197 (2004) (footnotes omitted).

> Under normal conditions, the tear volume in the conjunctival cul-de-sac is 7 to 9 µL in humans with a turnover rate of 0.5 to 2.2 µL/min, and the maximum volume that the conjunctival cul-de-sac can contain is estimated to be 30 µL. Commercial eyedroppers typically deliver between 25.1 and 56.4 µL; with an average drop volume of 39 µL. This sudden increase in volume in the conjunctival cul-de-sac and the irritant properties of the drug cause rapid reflex blinking and increased tear secretion. Most of the drug leaves the conjunctival cul-de-sac through the lacrimal drainage system and the excess is spilled onto the cheeks.[13]

The lacrimal or nasolacrimal drainage system is the route by which tears are drained from the eye through the tear duct into the nasal cavity and from there into the bloodstream.

58. A pharmacy and pharmaceutical textbook entitled *Drug Delivery and Targeting for Pharmacists and Pharmaceutical Scientists* ("Drug Delivery textbook") summed up these principles as follows:

> Under normal conditions the human tear volume is about 7-9 µl and it is relatively constant. The maximum amount of fluid that can be held in the lower eyelid sack is 25-30 µ1, but only 3µl of a solution can be incorporated in the precorneal film without causing it to destabilize. When eye-drops are administered, the tear volume is suddenly increased which can cause rapid reflex blinking. Most of the eyedrop is pumped through the lacrimal drainage system into the nasolacrimal duct, and some is spilled on the cheeks and splashed on the eyelashes.[14]

Equivalence of Effectiveness of Larger and Smaller Eye Drops

59. Consistent with these principles, scientific studies have shown that larger eye drops are no more effective than drops of 15 µL or smaller. In fact, larger eye drops may be even less effective than smaller drops.

60. In 1977, a scientist from the University of Kansas reported in the *Journal of Pharmaceutical Sciences* that a five-fold reduction in the volume of eye drops instilled in rabbits resulted in the same drug concentration at the active site in the eye as the larger drop. The study

[13] Deepta Ghate & Henry F. Edelhauser, *Barriers to Glaucoma Drug Delivery*, 17 J. Glaucoma 147, 147 (2008 (footnote omitted).

[14] Drug Delivery and Targeting for Pharmacists and Pharmaceutical Scientists (A.M. Hillery, A.W. Lloyd and J. Swarbrick, eds.) at 335 (2001).

concluded: "Therapeutically, it should be possible, by reducing the instilled volume by a factor of five, to reduce the dose administered by approximately a factor of three without altering drug concentration at the active site. This finding is significant and shows that the doses currently used for ophthalmic drugs are generally much larger than required."[15]

61. A 1984 study in *Archives of Ophthalmology* by scientists from the University of Arkansas similarly found that a 15 μL "minidrop" of the glaucoma drug clonidine was just as effective in reducing pressure inside the eye as a 70 μL drop.[16]

62. Three years later, scientists from the University of Texas Health Science Center and the University of Iowa College of Pharmacy reported in *Archives of Ophthalmology* that an 8 μL dilating eye drop had the same effect on the eyes of infants as a regular 30 μL drop.[17]

63. Alcon itself has shown that smaller eye drops are as effective as larger drops. In a study published in the *American Journal of Ophthalmology*, three scientists from Alcon, along with scientists from the Johns Hopkins School of Medicine, compared a 16 μL drop of a 0.5% concentration of the glaucoma drug apraclonidine hydrochloride to both a 30 μL drop of that concentration and a 30 μL drop of even a higher concentration, 1.0%. They found that the 16 μL drop achieved "a similar duration and magnitude of intraocular pressure reduction" to the larger drops. They concluded that "a 16-μL drop size was both effective and well-tolerated."[18]

64. Allergan has also proven that smaller eye drops are as effective as the larger drops on the market. In 1989, three scientists from Allergan, along with scientists from Yale

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[15] Thomas F. Patton, *Pharmacokinetic Evidence for Improved Ophthalmic Drug Delivery by Reduction of Instilled Volume*, 66 J. Pharmaceutical Sci. 1058, 1059 (1977).

[16] Gissur Petursson *et al., Treatment of Glaucoma Using Minidrops of Clonidine*, 102 Archives of Ophthalmology 1180 (1984).

[17] Mary G. Lynch *et al*., *Reduction of Phenylephrine Drop Size in Infants Achieves Equal Dilation With Decreased Systemic Absorption*, 105 Archives of Ophthalmology 1364 (1987).

[18] Vocci (1992) at 160.

University School of Medicine and other leading institutions, published "a randomized, double-masked, parallel, chronic study" comparing the effectiveness and safety of three different drop sizes, 20 μL, 35 μL and 50 μL, of the glaucoma drug levobunolol 0.5% (Allergan's branded "Betagan").[19] The authors found no difference in either safety or effectiveness. They stated: "In summary, we found that varying the drop size within the range of 20 to 50p.L has no clinically significant effect on either efficacy or safety of a beta blocker such as levobunolol." [20]

65. Based on the above studies and others, the peer-review literature uniformly indicates that smaller eye drops are at least as bioavailable in the eye as larger drops and may even be more bioavailable. Bioavailability is the extent and rate at which a drug accesses the desired site of action. A drug must be bioavailable to be effective.

66. In a thorough review of the world literature related to eye drop size that cited 117 references, Van Santvliet and Ludwig of the University of Antwerp stated that, in contrast with commercially available drops of 26-69 μL, "[f]rom bioavailability and toxicological points of view, even smaller eye drops, of 5 to 15 μL, should be instilled."[21] In this paper, published in *Survey of Ophthalmology*, they concluded: "The advantages of reduced drop sizes include equivalent or even improved ocular bioavailability and therapeutic response to the drug."[22]

67. Similarly, according to the *Drug Delivery* textbook quoted above, smaller drops drain away from the eye at a slower rate than larger drops and are therefore preferable: "The drainage rate of the solution is related to the instilled volume; the smaller the volume the slower the drainage rate. The instilled drop has been suggested to have an optimum volume

[19] Arthur D. Charap et al., *Effect of Varying Drop Size on the Efficacy and Safety of a Topical Beta Blocker*, 21 Ann. Ophthalmol. 351 (1989).

[20] Charap at 356.

[21] Van Santvliet and Ludwig (2004) at 197.

[22] Van Santvliet and Ludwig (2004) at 198.

of 8-15 µl. However, the typical volumes delivered by commercial eyedroppers are in the range of 35-56 µl."[23]

Larger Eye Drops Present a Greater Risk of Systemic Side Effects Compared to Smaller Drops

68. Most of the excess drug contained in Defendants' prescription eye drops leaves the eye through the lacrimal or tear duct and enters the body's systemic circulation without first undergoing metabolic inactivation in the liver. One researcher states: "Sixty to 80 per cent of the dose of an eyedrop will be absorbed systemically though the nasolacrimal duct and nasal mucosa without first-pass metabolism."[24]

69. The 1989 Allergan study[25] described this process and related it to the therapeutic index of ophthalmic drugs. The therapeutic index is the balance between the desired result (*i.e.*, treatment of disease) and the risk of harm (*i.e.*, side effects). As one author stated, "[a] major goal of any therapy is to improve the therapeutic index, *i.e.*, enhance the desired result while minimizing the risk."[26] The Allergan study stated:

> Since the normal human adult lacrimal lake is approximately 7 µL, commercial eyedrops can increase the volume of fluid in the eye initially by more than seven times. The excess fluid can roll down the cheek and be a nuisance to the patient. Of greater medical importance is the absorption of the excess drug through nasolacrimal drainage.
>
> The pharmacologic effect of absorption is similar to an intravenous injection. The drug enters the bloodstream as a bolus and bypasses the initial hepatic inactivation that occurs with oral medication. Systemic absorption of ocular medications is of particular concern for drugs such as beta blockers that have potent systemic effects.

[23] Drug Delivery and Targeting for Pharmacists and Pharmaceutical Scientists at 335.

[24] A. Cox, *Systemic Effects of Ocular Drugs*, 2002 Adverse Drug Reaction Bulletin 823, 823.

[25] Charap.

[26] Mary G. Lynch, *Reducing the Size and Toxicity of Eye Drops*, Research to Prevent Blindness Science Writers Seminar 20 (1988).

> Results of studies in both rabbits and humans support the hypothesis that administering a given quantity of ophthalmic medication in a reduced drop volume may enhance ocular bioavailabilitv, decrease systemic absorption and improve the therapeutic index. Other studies suggest that reducing the drop size of existing medications with no compensatory increase in concentration may reduce systemic absorption without sacrificing ocular efficacy. [27]

70. Those authors also offered an explanation for why the smallest drops that they studied, which were 20 µL, were not safer than the larger drops they studied, 35 and 50 µL. They suggested that improved safety does not occur unless the drops are smaller than 20 µL. They stated: "[C]linical changes may not be detectable unless the drop-size volume is decreased below a critical volume."[28]

71. An article by scientists from the Department of Ophthalmology of Truman Medical Center and the University of Missouri-Kansas City concurred that smaller drops would improve the therapeutic index: "Alteration of eyedrop delivery systems and alteration of the medication's physical properties to produce smaller drops could greatly diminish the cost of topical glaucoma therapy and improve the therapeutic index."[29]

72. The principle that smaller eye drops have a lower potential for toxic side effects than larger drops has actually been known since the 1970's. In 1977 a scientist from the Department of Pharmaceutical Chemistry, School of Pharmacy, University of Kansas stated in the Journal of Pharmaceutical Sciences: "By reducing the instilled volume and, hence, substantially decreasing the applied dose, the potential for toxic effects is reduced while drug concentration in the eye is maintained."[30]

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[27] Charap at 351-52.

[28] Charap at 355.

[29] Lederer (1986) at 694.

[30] Patton (1977) at 1059.

73. According to the *Drug Delivery* textbook quoted above, "nasolacrimal drainage is the major factor contributing to precorneal drug loss and systemic side-effects. The local/systemic effect balance can be improved by reducing the size of the eyedrop, and tips capable of delivering a drop of 8-10 µl have been designed by varying the relationship between the inner and outer diameters of the end of the tip."[31]

74. Consistent with that principle, the Alcon study that compared 16 and 30 µL drops, found that the smaller drops were "[t]he best tolerated."[32]

75. According to another study, systemic effects from ocular medication may go undiagnosed but are still experienced by the patient. In the case of β-andrenoceptor antagonists such as timolol maleate (Merck's branded Timoptic products), levobunolol hydrochloride (Allergan's Betagan) and other drugs used for glaucoma, systemic effects can include respiratory effects such as bronchospasm; cardiovascular effects such as palpitation, reduced blood pressure and slowed heart rate; and central nervous system effects such as depression, anxiety, disorientation and confusion. The elderly are at increased risk of these effects. A class of eye drops called α_2-adrenoreceptor agonists, such as brimonidine (Allergan's Alphagan and Alphagan-P), can cause systemic effects such as systemic hypotension, headaches, fatigue, somnolence and dry mouth.[33]

76. A table in a pharmacology textbook[34] lists the following systemic effects caused by two classes of glaucoma medications:

[31] Drug Delivery and Targeting for Pharmacists and Pharmaceutical Scientists at 339.

[32] Vocci (1992) at 154.

[33] Cox (2002).

[34] *Clinical Ocular Pharmacology* at 9 (Jimmy D. Bartlett & Siret D. Jaanus, eds., 5th ed. 2008).

Clinically Significant Systemic Effects Caused by Ocular Medications

Ocular Drug	Clinical Circumstance Under Which Adverse Effect Occurs	**Systemic Effect**
β-Blockers	Treatment of open-angle glaucoma	Decreased cardiac rate, syncope, exercise intolerance, bronchospasm, emotional or psychiatric disorders
Brimonidine	Treatment of open-angle glaucoma	Dry mouth, central nervous system effects including fatigue, lethargy

β-Blockers include Alcon's Betoptic-S, Allergan's Betagan, Merck's Timoptic, Timoptic-XE and Cosopt (a combination of timolol and dorzolamide), B+L's Istalol, and generic timolol maleate and levobunolol. Brimonidine is the generic name for Allergan's Alphagan P. Allergan's Combigan is a combination of the β-Blocker timolol and brimonidine. Merck's Cosopt and Prasco's Dorzolamide/Timolol are also combination products containing timolol.

77. Prostaglandins and prostaglandin analogues, which include Alcon's Travatan and Travatan Z, Allergan's Lumigan, and Pfizer's Xalatan, have systemic side effects including "occasional headache, precipitation of migraine in susceptible individuals, skin rash and mild upper respiratory tract symptoms."[35] In addition, their excessive size causes a risk of local side effects such as lengthening, thickening and hyperpigmentation of eyelashes, darkening of the iris, and hyperpigmentation of the skin around the eye.[36]

Drops Should Be No Larger Than 15 µL

78. From the standpoint of bioavailability and reducing risk of side effects, eye drops no larger than 5-15 µL should be used. Any amount in excess of that range is totally wasted.

79. This principle has been known for many decades by Allergan as well as the scientific world. In 1973, Allergan financially supported a paper published by scientists from the

[35] J.J. Kanski, Clinical Ophthalmology: A Systematic Approach (2007)

[36] Id.

School of Pharmacy, University of Wisconsin-Madison, in the *Journal of Pharmaceutical Sciences*. According to these authors, "to maximize activity of drugs in humans, the drop size of ophthalmic delivery systems ought to be reduced from its present 50-75-µl. drop to at most a 5- or 10-µL drop."[37]

80. More recently, citing six references spanning more than two decades, the scientists from the University of Antwerp quoted above stated: "It has been suggested that a decrease in drop size, to between 5 µl and 15 µl, would reduce the amount of overflow, the rate of drug loss through drainage, the incidence of systemic side effects, and the cost of therapy."[38]

81. In another paper, those same scientists stated: "The drop size of commercially available ophthalmic solutions ranges from 25 to 70 µL with an average of about 40 µL. From a biopharmaceutical and toxicological point of view, however, it is important to instill small volume eye-drops, with an ideal volume of 5-15 µL."[39]

82. Scientists from McGill University in Montreal and Fluminense Federal University in Rio de Janeiro, writing in *the Journal of Clinical Pharmacy and Therapeutics*, likewise advocated smaller drops. "Concerning bioavailability and toxicity," they stated, "drops of 5-15 µL would be ideal."[40]

83. In a study published in the *Journal of Glaucoma* in 2008, the scientists from Emory University quoted above also recommended the use of smaller drops, stating: "Reducing

[37] Sukhbir S. Chrai *et al.*, *Lacrimal and Instilled Fluid Dynamics in Rabbit Eyes*, 62 J. Pharmaceutical Sci., 1112 at 1112 (1973).

[38] Van Santvliet & Ludwig (2004) at 198.

[39] Luc Van Santvliet and Annick Ludwig, *Influence of the Dropper Tip Design on the Size of Eye-drops* (2001) (footnotes omitted).

[40] M.P. Ventura et al., *Cost Considerations of the New Fixed Combinations for Glaucoma Medical Therapy*, 30 J. of Clinical Pharmacy and Therapeutics 251, 253 (2005).

the drop size to 5-15 μL would reduce overflow, decrease systemic absorption, reduce cost of therapy while maintaining equivalent or even enhanced ocular bioavailability."[41]

84. On information and belief, at all times relevant hereto, Defendants were well-aware of these principles and knew or should have known that the dispensing of prescription eye drops exceeding 15 μL would result in unnecessary wastage of medicine, an increased risk of systemic side effects, and an unnecessary and wasted therapeutic expense to patients and/or their third party payors.

85. Indeed, Allergan has stated as much to the scientific community on several occasions. In a 2011 medical e-book on glaucoma, an Allergan scientist wrote: "Smaller size drops, on the order of 15 μL, have an efficacy and bioavailability equivalent to larger drops, without the waste. In fact, drops of this size are preferable, as they minimize systemic exposure and wastage."[42]

86. Five years earlier, two Allergan employees co-authored, and Allergan funded, a paper in the Journal of Ocular Pharmacology and Therapeutics that stated: "Studies have shown that the bioavailability and efficacy of drops as small as 15 μL are equivalent to those of larger drops. Therefore, smaller drops would be preferable to minimize systemic exposure and spilled or wasted medication."[43]

87. Even earlier, in 1989, three Allergan scientists, along with co-authors from institutions such as Yale University School of Medicine, published the study described above in which they found that drops of 20 μL were just as effective as drops of 50 μL; in that paper they favorably cited three studies that "suggest that reducing the drop size of existing medications

[41] Ghate & Edelhauser (2008) at 147.

[42] J. Walt (2011) at 208.

[43] Fiscella *et al.* (2006) at 478.

with no compensatory increase in concentration may reduce systemic absorption without sacrificing ocular efficacy."[44] Nevertheless, neither Allergan nor any of the other Defendants reduced the drop size of their existing medications.

Defendants' Eye Drops Are Much Larger Than 15 µL

88. As part of a scheme to increase profits by selling more product than consumers want or need, each Defendant sells ophthalmic medication in bottles that instill drops that are two and three times 15 µL or more.

89. Research has demonstrated that "commercial eyedroppers typically deliver between 25.1 and 56.4 µL; with an average drop volume of 39 µL."[45]

90. As the University of Antwerp paper quoted above states, citing eight separate studies, "[o]phthalmologists and hospital pharmacists performing studies to determine the cost per dose and per bottle of eye medication reported eye drop volumes ranging from 26.4 µL up to 69.4 µL."[46]

91. Studies published in respected peer-reviewed medical and pharmaceutical journals such as the *American Journal of Ophthalmology* and the *Journal of Clinical Pharmacology and Therapeutics* published in 1999, 2003, 2005, and 2008 have shown that Defendants' prescription eye drops greatly exceeded the optimum size.[47] The 1999 paper was financially supported by Merck. These studies provided data from which one can calculate the

[44] Charap (1989) at 352.

[45] Ghate & Edelhauser at 147.

[46] Van Santvliet & Ludwig (2004) at 197.

[47] Nathan R Rylander & Steven D. Vold, *Cost Analysis of Glaucoma Medications*, 145 Am. J. Ophthalmology 106-113 (2008); Ventura *et al.* (2005); Richard G. Fiscella *et al., Medical Therapy Cost Considerations for Glaucoma*, 136 Am. J. Ophthalmology 18-25 (2003); Richard G. Fiscella *et al., Cost Considerations of Medical Therapy for Glaucoma*, 128 Am. J. Ophthalmology 426-433 (1999). Some studies report the number of drops per milliliter; drop size is determined by dividing one milliliter by the number of drops per milliliter.

drop sizes; they show that Defendants' drops uniformly exceeded 15 μL by large amounts (numbers represent the drop sizes in μL):

Alcon.

Betoptic-S:

Bottle Size	1999	2003	2008
2.5 mL	NA	NA	43
5 mL	34	34	40
10 mL	39	39	38
15 mL	33	33	37

Timolol Maleate (Falcon):

Bottle Size	1999	2003	2008
5 mL	35	35	32
10 mL	32	32	34
15 mL	34	34	32

Timolol Maleate gel forming (Falcon):

Bottle Size	1999	2003	2008
5 mL	35	35	32
10 mL	32	32	34
15 mL	34	34	32

Azopt:

Bottle Size	1999	2003	2008
5 mL	41	41	34
10 mL	39	39	34
15 mL	40	40	31

Travatan:

Bottle Size	2003	2008
2.5 mL	29	26
5 mL	NA	25

Travatan Z:

Bottle Size	2008
2.5 mL	29
5 mL	30

Allergan.

Betagan:

Bottle Size	1999	2003
5 mL	45	45
10 mL	48	48
15 mL	49	49

Alphagan/Alphagan P:

Bottle Size	1999	2003	2008
5 mL	47	47	43
10 mL	42	42	44
15 mL	46	46	43

Lumigan:

Bottle Size	2003	2008
2.5 mL	27	31
5 mL	29	31
7.5 mL	29	31

Combigan:

Bottle Size	2005
5 mL	33

Pfizer.

Xalatan

Bottle Size	1999	2003	2008
2.5 mL	31	36	34

B+L.

Levobunolol:

Bottle Size	1999	2003
5 mL	52	52
10 mL	50	50
15 mL	51	51

Optipranolol:

Bottle Size	1999	2003	2008
5 mL	38	38	38
10 mL	40	40	40

Timolol Maleate:

Bottle Size	1999	2003	2008
5 mL	31	31	NA
10 mL	29	29	NA
15 mL	31	31	NA

Merck.

Timoptic:

Bottle Size	1999	2003	2008
2.5 mL	31	NA	NA
5 mL	34	30	36
10 mL	31	32	34
15 mL	32	32	NA

Timoptic XE:

Bottle Size	1999	2003	2008
2.5 mL	42	42	NA
5 mL	38	38	46

Trusopt:

Bottle Size	1999	2003	2008
5 mL	39	38	NA
10 mL	39	36	43

Cosopt:

Bottle Size	1999	2003	2005	2008
5 mL	37	34	40	NA
10 mL	39	35	NA	45

Akorn:

Bottle Size	1999	2003		
5 mL	33	33		
10 mL	32	32		
15 mL	31	31		

92. Documents of the United States Food & Drug Administration, available at the FDA's "Drugs@FDA" web site, also show that Defendants' prescription eye drops are well over 15 μL. FDA Pharmacological, Medical and other Reviews of these drugs show the following drop sizes (numbers are in μL):

Alcon

Brimonidine tartrate 0.015%: 41.8

Travatan: 25

Travatan Z: 25

Vigamox: 38

Allergan

Alphagan: 35

Acular LS: 50

Combigan: 35

Elestat: 30-35

Lastacaft: 35

Lumigan 0.3%: 30

B+L/Ista

Alrex: 50

Besivance: 37

Xibrom/Bromday: 50

Istalol: 50

Lotemax: 50

Zylet: 50

Merck

Azasite: 50

93. Other FDA reviews do not directly specify drop size, but they provide data from which the following drop sizes can be calculated (numbers are in μL):

Alcon

Azopt: 50

Moxeza: 50

Nevanac: 50

Allergan

Alocril: 40

Zymaxid: 40

B+L/Ista

Bepreve: 50

Large Eye Drops Cause Substantial Injuries to Consumers

94. Defendants' practices of selling prescription eye drops in dispensers that emit drops larger than 15 µL cause substantial injury, both because they compel Class Members to spend more money on their therapy than if the drops were 15 µL and because larger eye drops cause unwarranted health and safety risks.

95. If the sizes of Defendants' prescription eye drops were limited to the maximum effective size of 15 µL, the medication in the bottles would last longer and Class Members would spend substantially less on their therapy than they do with larger, substantially wasted, eye drops. This principle is not only obvious on its face, but it has been stated repeatedly in the medical and pharmaceutical literature.

96. In a 1986 study published in the *American Journal of Ophthalmology* that reported that drop sizes of several commercial glaucoma medications averaged 39 µL, the authors stated: "In addition to the pharmacologic advantages of a smaller drop, there are significant economic implications." The authors described those economic implications as follows: "If the eyedrops could be reduced to 15 µL (shown to be effective with clonidine eyedrops), the average bottle would yield 1,033 drops, sufficient for 36.9 weeks of therapy." By contrast, the authors found that an average bottle of a glaucoma drug with drops of 39.8 µL, yielded 389 drops, good for only 13.9 weeks of therapy. The authors concluded: "Alteration of eyedrop delivery systems and alteration of the medication's physical properties to produce

smaller drops could greatly diminish the cost of topical glaucoma therapy and improve the therapeutic index."[48]

97. Similarly, the Emory University study quoted above stated: "Reducing the drop size to 5-15 μL would reduce overflow, decrease systemic absorption, reduce cost of therapy while maintaining equivalent or even enhanced ocular bioavailability."[49]

98. Allergan agrees that smaller drops would result in lower costs for patients and managed care providers. The 2006 study by Allergan states: "Obviously, a smaller drop size would mean that more doses could be dispensed from each bottle of medication, providing cost savings to patients and managed care providers."[50]

99. Merck has publicly indicated that the design of the dropper tips, which determines drop size, is an important influence in the cost of eye drop therapy. In a 1996 paper, its scientists stated: "Many factors influence the daily cost of therapy for eyedrops. In a study of drop size, Brown *et al.* concluded the design of eyedropper tips is important because it determines the size and flow rate of the bottle."[51]

100. The amount of overpayment that consumers and other payors have been compelled to make because of overly large prescription eye drops is substantial. For example, according to Rylander (2008), the average drop size for Allergan's glaucoma drug Alphagan P 0.15% in a 5 mL bottle was 43 μL, and the bottle held 5.17 mL of medication. At the recommended dose of one drop in each affected eye three times daily, a 5 mL bottle would last a patient with bilateral glaucoma 20 days. That patient would go through 18.25 bottles in a year.

[48] Lederer at 694 (1986).

[49] Ghate & Edelhauser (2008) at 147.

[50] Fiscella *et al.* (2006) at 478.

[51] David Hartenbaum et al., *Quantitative and Cost Evaluation of Three Antiglaucoma Beta-Blocker Agents: Timoptic-XE versus Two Generic Levobunolol Products*, II Am. J. of Managed Care 157, 162 (1996).

In July 2013, a 5 mL bottle of Alphagan P at www.drugsdepot.com cost $104.99.[52] A year's course of treatment would therefore cost approximately $1,915. However, approximately 65% of the medication, the amount over 15 µL, would be wasted. If the drops had been only 15 µL, the patient would have needed only 6.4 bottles a year. The unneeded medication, the difference between 18.25 bottles and 6.4 bottles, would cost the patient approximately $1,245 a year.

101. A similar analysis shows that the use of Alcon's Betoptic S, B+L's Istalol, Pfizer's Xalatan and Merck's Cosopt can cost a consumer $596, $1103, $546, and $644 a year respectively in wasted medication.

102. In the aggregate, the amount of money spent on inherently wasted medication is substantial. For example, the web site www.drugs.com estimates that in 2010 alone, retail sales of Pfizer's Xalatan in the United States exceeded $500 million.[53] But only 44% of each 34 µL drop was useful in treating the patients' glaucoma. The 56% of the medication that went to waste cost $280 million in that one year alone.

103. The overall amounts that consumers and third-party payors have been compelled to spend on medication that provided no benefit because of the unfair, unethical and unconscionable practices of these Defendants can be multiplied many times over when all of the Defendants' prescription eye drops are considered.

104. Furthermore, as described above, the large drop sizes of Defendants' prescription eye drops cause much of the medication to pass through the tear duct and, without first being metabolically inactivated, enter the patient's circulation where it causes a risk of systemic side effects.

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[52] http://www.drugsdepot.com/catalog.php/drugsdepot/dt/pd2012060/Alphagan_P_.15_Drops_1X5_ml_Mfg._By_-Allergan_Inc (accessed December 5, 2013).

[53] http://www.drugs.com/top200.html (accessed December 5, 2013).

105. In addition, the large drop sizes of these products contributes to a situation where many glaucoma patients run out of medication before their insurance or managed care plan will reimburse them for a new bottle of medication. They thus have to choose between paying the full price of the drug themselves or going without. However, because of the high prices of these medications, many consumers cannot afford to pay for them without third-party reimbursement. Therefore, they either go without their needed medications or attempt to "ration" them by, for example, using them every other day rather than the prescribed daily use.

106. As a result, because they cannot afford to use their medication every day as prescribed, these consumers run the risk of a decline in their eyesight or going completely blind.

Consumers Could Not Reasonably Have Avoided This Injury

107. Consumers could not reasonably have avoided the injuries they sustained as a result of using prescription eye drops that are larger than the capacity of their eyes. There are several reasons for this.

108. First, individual patients do not choose which drugs to take; they are prescribed their drugs by their physicians. Once the doctor has prescribed a prescription eye drop, the patient has no alternative other than rejecting the physician's advice and foregoing the treatment entirely.

109. Moreover, wastage cannot be avoided by switching to an alternative product, because all prescription eye drops are substantially larger than 15 µL and therefore lead to wastage.

110. Besides that, it is impossible to instill less than one eye drop into an eye. Thus, a consumer must consume the entirety of the excessively large drop supplied by the manufacturer, even though only a portion provides any benefit.

There Are No Countervailing Benefits from Eye Drops that Are Larger than the Capacity of the Eye

111. Furthermore, the injuries of Plaintiffs and Class Members are not outweighed by any offsetting consumer or competitive benefits. In fact, there are no consumer or competitive benefits from the excessive sizes of Defendants' eye drops

112. Thus, there is no valid, legitimate or ethical reason why Defendants have not supplied prescription eye drops in bottles that dispense drops no larger than 15 μL. The only reason Defendants make their eye drops as large as they are is to sell more product.

The Sizes of Defendants' Eye Drops Are Within Their Control

113. Defendants are, and have been, able to sell their medications in dispensers emitting smaller drops. The size of the drops emitted by the dropper depends on the specific dropper tip used, a factor entirely within the control of the manufacturer. In 1988, Dr. Mary Lynch of Emory University told the Tenth National Science Writers Seminar in Ophthalmology, sponsored by the organization Research to Prevent Blindness: "The size of an eyedrop is determined by the dimensions of the eyedropper tip: the inner diameter or hole and the outer diameter of the tip."[54]

114. This is a principle that Allergan recognizes. In his e-book chapter, the Allergan scientist quoted above stated that the size of eye drops "depends on the design and dimensions of the dropper tip …."[55]

115. Thus, Defendants could substantially reduce drop size simply by changing the design and dimension of the dropper tip. In 1985, the Wilmer/Johns Hopkins and Bascom Palmer scientists mentioned above reported that "[c]hanges in the dimensions of an eyedropper

[54] Lynch (1988) at 20

[55] Walt (2011) at 208.

tip can alter eyedrop volume markedly." By experimenting with different dimensions, they were able to create dispensers that emitted drops of only 11 μL and 19 μL. To assist anyone who wanted to manufacture these dispensers to make smaller drops available commercially, they published the dimensions of their newly created tips.[56]

116. The authors also included the following photograph comparing a standard-sized eye drop to a 19 μL drop that they created:

Fig. 2 (Brown, Hotchkiss, and Davis). A standard-sized eyedrop (left) from a commercial eyedropper tip compared to a smaller eyedrop produced by one of the smaller tips we used (outer diameter = 0.047 inch; inner diameter = 0.020 inch).

117. On information and belief, none of the Defendants has ever publicly criticized this study or suggested that it has any limitations. Indeed, Merck recognizes its validity. In a paper that showed the significant effect drop size can have on the costs consumers bear for eye drops, Merck's employees stated: "Many factors influence the daily cost of therapy for eyedrops. In a study of drop size, Brown *et al.* concluded the design of eyedropper tips is important because it determines the size and flow rate of the bottle."[57]

118. Three years after the Brown study was published, one of its co-authors, Dr. Mary Lynch, told the Tenth National Science Writers Seminar in Ophthalmology that she was by then

[56] Brown *et al.* (1985).

[57] Hartenbaum (1996) at 162.

able to create droppers that would consistently emit drops of only 8 to 10 μL and could thereby enhance the desired result from eye drops. She stated:

> A major goal of any therapy is to improve the therapeutic index, *i.e.*, enhance the desired result while minimizing the risk. One way to improve the therapeutic index of an eyedrop is to reduce the size of the eyedrop. By varying the relationship between the inner and outer diameters of the end of the tip, the size of an eyedrop can be altered. We have designed eyedrop tips that can consistently deliver eyedrops as small as 8 to 10 microliters.[58]

119. In 1992, scientists from Alcon co-authored a paper, described above, in which a smaller drop size was compared to a standard drop. For the smaller drop, the authors used "a potentially commercially available eyedrop bottle that delivers a 16-μl drop size."[59] The authors reported that the users of that bottle "agreed it was easier to squeeze and deliver one drop with this bottle and therefore preferred the new eyedrop bottle to the conventional eyedrop bottle."[60] Nevertheless, Alcon has never sold eye drops using that bottle.

120. Recently, a standard textbook in the field, *Clinical Ocular Pharmacology*, reported that "it is practical to dispense accurately measured drops as small as 2 to 5 μL by reducing the bore size of commercial dropper dispensers."[61]

121. Nevertheless, Defendants have persisted in selling their drops in droppers that emit much larger drops.

[58] Lynch (1988) at 21.

[59] Vocci (1992) at 157.

[60] Vocci (1992) at 159.

[61] *Clinical Ocular Pharmacology* at 18 (Jimmy D. Bartlett & Siret D. Jaanus, eds., 5th ed. 2008).

Other Factors that Might Influence the Size of Eye Drops Do Not Prevent Defendants from Reducing the Sizes of their Eye Drops

122. Although there are other factors, such as the viscosity and surface tension of the liquid and the dispensing angle that can influence the size of eye drops, none of those factors prevents Defendants from reducing drop size by changing their dropper tips.

123. For any given topical ophthalmic medication, the viscosity and surface tension of the liquid are a constant and do not prevent Defendants from reducing drop size by changing the dimensions of their dropper tips.

124. Nor does any variability because of the dispensing angle prevent Defendants from reducing drop size. Studies have found that the dispensing angle has either no effect or a small effect on drop size.

125. A 1992 study compared the size of drops when the bottle was held vertically and at 135° (*i.e.*, halfway between vertical and horizontal).[62] The results for Alcon's Betoptic and Betoptic S, B+L's Optipranolol, and Merck's Timoptic "provided a consistently measured dose regardless of the angle at which the bottle was held …." The drops of the fifth product, Allergan's Betagan, were 14.5% smaller when dispensed obliquely than when dispensed vertically at room temperature but were still more than three times the ideal size (47 μL vs. 55 μL).

126. A study by Merck found no statistically significant difference in the drops of B+L's Levobunolol when drops were dispensed vertically or at an oblique angle for all three bottle sizes. Nor was there a significant difference for Merck's own product, Timoptic-XE.[63]

[62] S.F. Ball et al., *Cost of B-Adrenergic Receptor Blocking Agents for Ocular Hypertension*, 110 Arch. Ophthalmol. 654 (1992).

[63] Hartenbaum (1996) at 161.

127. The two scientists from the University of Antwerp quoted above have studied the differences between holding a bottle vertically and at 45°, using at least four different commercially available dispenser tips and 10 separate solutions that they formulated for experimental purposes.[64] Depending on the dispenser-solution combination, they found either a negligible difference or a variance of between 2% and about 10%.

128. The 2006 Allergan study[65] compared drop sizes when dispensed vertically and at 45° of bimatoprost (the generic name for Allergan's Lumigan), latanoprost (Pfizer's Xalatan), and travoprost (Alcon's Travatan). The differences between vertical and 45° were 5.1%, 6.2%, and 19.4% for the three drugs respectively.[66]

129. At the time of that study, the Allergan authors believed that these differences were so significant that patients should be instructed about the proper angle at which to hold the bottle. But Allergan apparently no longer believes that to be the case. Thus, in their published paper, the Allergan authors stated:[67]

> Health care providers are urged to instruct glaucoma patients in the most efficient method of instillation for their prostaglandin analogs. For bimatoprost and latanoprost, the most efficient method is instillation with the bottle held vertically, with 45 degrees nearly as efficient. For travoprost, the most efficient method is instillation at 45°.

Bimatoprost is the generic name for Allergan's brand-name Lumigan.

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[64] L. Van Santvliet and A. Ludwig studies: *Influence of the physico-chemical properties of ophthalmic viscolysers on the weight of drops dispensed from a flexible dropper bottle*, 7 Eur. J. Pharm. Sci. 339 (1999*); Dispensing Eye Drops from Flexible Plastic Dropper Bottles. Part II: Influence of the physico-chemical properties of the formulation and the manipulation technique by the patient*, 61 Pharm. Ind. 194 (1999); and *Influence of the Dropper Tip Design on the Size of Eye-Drops*, 63 Pharm. Ind. 402 (2001); Van Santvliet and Ludwig (2004).

[65] Fiscella (2006).

[66] The authors said they also measured drops when dispensed horizontally but did not explain how that would even be possible as the quantity of medication in the bottle decreased. Van Santvliet and Ludwig say that "[i]n practice, the angle at which the bottle is held varies from 90° to 30°. Van Santvliet, *Dispensing Eye Drops* (1999) at 194.

[67] Fiscella (2006) at 481.

130. On information and belief, Allergan no longer believes that the dispensing angle significantly affects drop size. This allegation is based on the fact that, although Allergan instructs consumers about obvious aspects of eye drop use, it does not currently instruct consumers about the dispensing angle. For example, Allergan maintains a web page called, "How to Use Lumigan 0.01% Drops."[68] That page has detailed instructions and "tips," including such obvious measures as blotting away excess liquid on the skin and waiting until blurry vision clears before driving. However, the page says nothing about the angle of the bottle, something Allergan would surely include if it believed it was as important and helpful as, for example, telling consumers to wipe away excess liquid and not driving with blurry vision.

The FDA Does Not Prevent Defendants from Changing the Size of Eye Drops

131. As the facts alleged in this Complaint demonstrate, a reduction in eye drop size to 15 µL would not have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product. Therefore, such a reduction would not be a "major change" requiring prior FDA approval pursuant to 21 C.F.R. § 314.70. Nor does the FDA regulate the economics of drug use. For those reasons, the FDA does not require or specifically permit Defendants are to make their eye drops so large that it leads to wastage of medication.

132. In fact, Defendants have not been constrained by any legal or regulatory restriction of the FDA from changing the sizes of their eye drops. In fact, in some instances they have changed the sizes of their eye drops significantly and have done so without first obtaining FDA approval, according to documents posted on the FDA's web site.

[68] http://www.lumigan.com/AboutLumigan/UsingDrops.aspx (accessed December 5, 2013).

133. For example, published studies from 2003 and 2008 show that Merck's Cosopt increased in size over that period from 34 µL (29.2 drops per mL) to 45 µL (22.3 drops per mL).[69]

134. Those same studies show that Alcon's Azopt drops were substantially smaller than their earlier volume according to FDA documents. As described above, a 1997 document on the FDA web site contains data that indicate that a drop of Azopt was 50 µL, but Azopt drops were shown to be 40 µL (25.1 drops per mL) in 2003 and were reduced further to 34 µL (29.6 drops per mL) by 2008.[70]

135. In the case of Alcon's Travatan Z, the drop size according to the FDA's review in 2005, based on what Alcon had told it, was 25 µL. Nevertheless, just a few years later, Rylander et al.[71] measured the size of Travatan Z drops as 30 µL, meaning that consumers and third-party payors were compelled to pay for 20% more medication than Alcon had stated to the FDA.

136. The FDA maintains a web site, called "Drugs@FDA," that can be used for "viewing the approval history of a drug."[72] That web site contains no applications for, or approvals of, the above changes in drop size of Cosopt, Azopt or Travatan Z. Thus, FDA approval of those changes was apparently not required.

137. Nor does the FDA's approval of a product's label, even where the label reflects a certain drop size, mean that the company cannot change the drop size without FDA's prior approval. This fact is shown by the case of Pfizer's Xalatan. The FDA's web site contains the

[69] Compare Fiscella et al. (2004) to Rylander (2008).

[70] Compare Fiscella et al. (2004) to Rylander (2008).

[71] Rylander (2008).

[72] *See* http://www.fda.gov/Drugs/InformationOnDrugs/ucm075234.htm#purpose (accessed December 5, 2013).

approved labels for Xalatan for the period 2001 to the present.[73] Like the label of every other medication subject to this lawsuit, these labels do not mention the size of the drop, but they are rare examples of labels that contain data from which the size of the drop can be calculated. Each of those labels states that the amount of the active ingredient in a drop of Xalatan was 1.5 µg and that the concentration of that ingredient in the solution was 50 µg/mL. If accurate, that would mean that each drop was 30 µL.[74] However, Fiscella et al.[75] found that Xalatan drops were 20% larger than that at 36 µL, and Rylander et al.[76] found that they were 34 µL. This also means that amount of medication per Xalatan drop was up to 20% more than the 1.5 µg stated on the Xalatan labels.

138. Yet Xalatan's label did not change as its drop size changed, and the FDA's Drugs@FDA web site shows no application for, nor FDA approval of, these changes in drop size or in the amount of medication per drop. Thus, Pfizer was able to change the Xalatan drop size without FDA's prior approval and without changing its label.

139. Based on Xalatan's annual retail sales of $500 million as described above, end payors in the United States paid approximately $60 million in just one year for excess medication from using 34-µL Xalatan drops compared to what they would have paid if the drops had been "only" 30 µL as suggested by the Xalatan label.

140. Moreover, according to research presented in 2012 to the annual meeting of the Association for Research in Vision and Ophthalmology ("ARVO"), by that year Pfizer had

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[73] *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_Approval-History#apphist (accessed December 5, 2013) (search for "Xalatan" to obtain the approved labels).

[74] At 1.5 µg per drop and 50 µg per mL (or 1000 µL), there are 33.3 drops per 1000 µL (50 divided by 1.5). Dividing 1000 µL by 33.3 drops yields a drop size of 30 µL.

[75] Fiscella (2003).

[76] Rylander (2008)

reduced the amount of the active ingredient per drop of Xalatan to 1.13 µg, 25% less than the 1.50 µg shown on the label.[77] If the amount of the active ingredient in a drop of Xalatan was 1.13 µg and the concentration of the active ingredient remained constant at 50 µg/mL, that means the drop size would have been only 23 µL. On the other hand, if the drop size had stayed the same, that means that the concentration of the drug in the solution had been reduced below what was set forth on the Xalatan label.

141. In either case, FDA regulations did not prevent Pfizer from making this change. The FDA's Drugs@FDA web site, which contains applications and approvals for changes in prescription drugs, shows no application by Pfizer, nor approval by the FDA, of these changes in the amount of active ingredient per drop. If Xalatan could, consistent with its obligations under FDA regulations, make these changes, there is no reason why it could not have reduced the size of the drops further to 15 µL consistent with its obligations under FDA regulations.

142. Nor are generic eye drops restricted to the same size as their brand-name equivalents. As the United States Supreme Court stated in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575. (2011), with respect to such aspects as a product's label, "generic drug manufacturers have an ongoing federal duty of 'Sameness.'" Thus, "[t]o obtain FDA approval, a generic manufacturer must ordinarily show, among other things, that its product has the same active ingredients as an approved brand-name drug; that 'the route of administration, the dosage form, and the strength of the new drug are the same' as the brand-name drug; and that its product is 'bioequivalent' to the brand-name drug. §§ 355(j)(2)(A)(ii), (iii), (iv)." 131 S. Ct. at 2583.

[77] Brian S, Jayat C, Desmis A, *et al*., *Pharmaceutical evaluation of the quality and delivered dose of US latanoprost generics,* Abstract presented at ARVO Annual Meeting, 2012.

143. That does not mean, however, that the FDA restricts the drop size of a generic prescription eye drop to be the same as its brand-name equivalent. In fact, they have been measured in published studies to have substantially different sizes and substantially different dropper tip dimensions. For example, Fiscella (1999) measured Merck's Timoptic XE as 40 µL and a Falcon generic version of this drug as only 31 µL.

144. Similarly, a 2011 study by scientists from the University of Toronto and University of Waterloo, Ontario, found Merck's Timoptic XE sold in the United States to be 38 µL and Falcon's generic equivalent to be 24 µL, 37% smaller.[78] The authors explained the difference by the differing dimensions of the bottles that dispensed these two drugs. Specifically, they pointed to the differences in the outer orifices of the dropper tips through which the fluid passes because "[t]he larger the outer orifice's diameter, the larger the cross-sectional area available for drop formation and, therefore, the larger the drop size."[79] They stated: "Outer orifice diameters of Canadian and American brand-name Timoptic XE bottles were approximately 3 times larger than those of the bottles of their generic equivalents; this significant difference helps to explain drop volume variability between the brand-name and the generic products."[80]

145. Another example of dramatically different bottle designs for a brand-name product and its generic equivalents can be seen with the glaucoma drug timolol maleate (brand-name: Timoptic). Below, taken from the manufacturers' product information on their web sites, are diagrams of the Timoptic bottle, as well as generic versions sold by Defendant Falcon and a generic manufacturer named Apotex.

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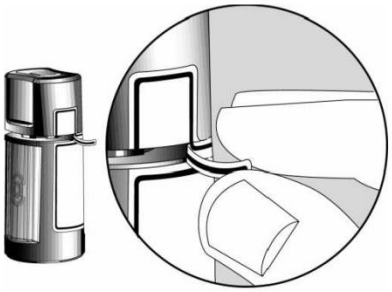
[78] Zaid N. Mammo et al., *Generic Versus Brand-Name North American Topical Glaucoma Drops*, 47 Can. J. Ophthalmology 55 (2011).

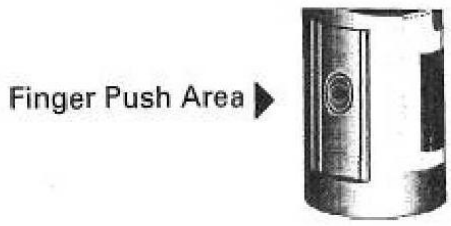
[79] *Id.* at 58.

[80] *Id.* at 57.

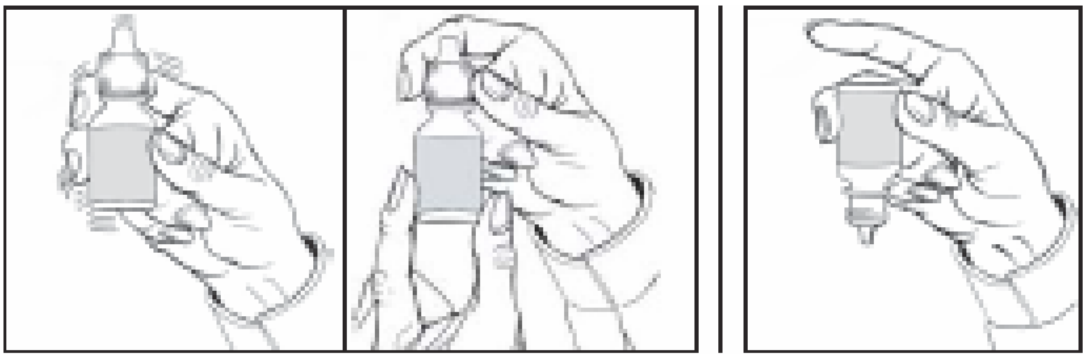
146. Not only are these bottles visually different, but unlike the other two, the Apotex bottle has a closed tip with a "spiked" cap that the patient uses to puncture the exit hole.

TIMOPTIC (BRAND-NAME) BOTTLE





FALCON'S TIMOLOL MALEATE (GENERIC) BOTTLE



APOTEX TIMOLOL MALEATE (GENERIC) BOTTLE

147. The above examples demonstrate that changes in dropper tip design and drop size are can be made consistent with FDA regulations. If generic manufacturers can, pursuant to their

FDA regulatory obligations, legally sell prescription eye drops with different bottle designs– as they do – and if they can provide drops that are 37% smaller than the brand-name equivalents of these drugs – as again they do – there is no reason why they, or brand-name manufacturers, could not legally sell their products in bottles that emit 15 μL drops. Yet, as shown above, they do not.

CLASS ACTION ALLEGATIONS:

148. Pursuant to Rule 23 of the Federal Rules of Procedure, Plaintiffs seek certification of the following Classes and Subclasses defined as follows:

149. **Alcon Class.** Plaintiffs Robert Gustavsen, Lee Wilburn and Mary Law seek to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), which collectively constitute the Alcon Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Alcon in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Alcon UDAP Sub-Class.")
>
> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Alcon in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Alcon Common Law Sub-Class.")

Excluded from the Alcon Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants,

counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

150. **Allergan Class.** Plaintiffs Joseph Cugini, Jackie Corbin and Cecelia Brathwaite seek to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), which collectively constitute the Allegan Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Allergan in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Allergan UDAP Sub-Class.")
>
> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Allergan in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Allergan Common Law Sub-Class.")

Excluded from the Allergan Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

151. **Pfizer Class.** Plaintiffs Demetra Cohen, Lee Wilburn and Jackie Corbin seek to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), which collectively constitute the Pfizer Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Pfizer in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Pfizer UDAP Sub-Class.")
>
> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Pfizer in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Pfizer Common Law Sub-Class.")

Excluded from the Pfizer Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

152. **Valeant Defendants Class.** Plaintiff Jackie Corbin seeks to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), which collectively constitute the Valeant Defendants Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Valeant in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Valeant UDAP Sub-Class.")
>
> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Valeant in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North

> Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Valeant Common Law Sub-Class.")

Excluded from the Valeant Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

153. **Merck Class.** Plaintiffs Jackie Corbin and Cecelia Brathwaite seek to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), all of which collectively constitute the Merck Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Merck in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Merck UDAP Sub-Class.")

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Merck in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Merck Common Law Sub-Class.")

Excluded from the Merck Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

154. **Prasco Class.** Plaintiff Jackie Corbin seeks to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), all of which collectively constitute the Prasco Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Prasco in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Prasco UDAP Sub-Class.")

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Prasco in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Prasco Common Law Sub-Class.")

Excluded from the Prasco Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

155. **Akorn Class.** Plaintiff Lee Wilburn seeks to represent all persons and entities who fall within one of the following subclasses (for each plaintiff, the respective subclass of his or her state), all of which collectively constitute the Akorn Class:

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Akorn in multi-dose dispensers and purchased within the states of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Akorn UDAP Sub-Class.")

> All persons and entities who paid all or part of the purchase price of prescription eye drops manufactured and sold by Akorn in multi-dose dispensers and purchased within the states of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin within the period of the applicable statutes of limitations prior to the filing of this lawsuit and up to the date of certification. ("Akorn Common Law Sub-Class.")

Excluded from the Akorn Class and Sub-Classes are officers, directors and employees of Defendants and any entity affiliated with or controlled by Defendants, counsel and members of the immediate families of counsel for Plaintiffs herein, and the judge presiding over this action and any member of the judge's immediate family.

156. **Numerosity.** Although the exact size of the Classes is currently unknown to Plaintiffs, the total number of Class Members in each class and subclass is so numerous that joinder of all Class Members would be impracticable. Accordingly, this putative class action satisfies Rule 23(a)(1).

157. **Commonality.** There is a well-defined community of interest in the questions of law and fact affecting Class Members, satisfying Rule 23(a)(2). Among the numerous questions of law or fact common to the Classes are the following:

A. What is the capacity of the human eye to hold dropped liquid?

B. When an eye drop that is larger than 15 μL is instilled in the eye, does the amount in excess of 15 μL have any therapeutic effect?

C. When an eye drop that is larger than 15 μL is instilled in the eye, does the amount in excess of 15 μL go to waste?

D. Do smaller size drops, on the order of 15 μL, have an efficacy and bioavailability equivalent to larger size drops, without the waste?

E. Does a portion of an eye drop in excess of 15 μL leave the eye through the tear duct and enter the systemic circulation without first being metabolically inactivated in the liver, leading to a risk of side effects?

F. Are drops of 15 μL preferable to larger drops, as they minimize systemic exposure, toxic side effects, and wastage?

G. Is there any medically sound reason to dispense eye drops in excess of 15 μL?

H. Is it feasible to make an eye dropper that will dispense smaller drops than the containers of Defendant's existing ophthalmic products do?

I. Did each Defendant engage in a scheme to increase its profits by packaging and selling its prescription eye drops in such a way that consumers were forced to buy more product than they needed?

J. Is it unfair, within the meaning of the Massachusetts Consumer Protection Act and the comparable consumer protection statutes of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia, to sell a product that, due to the design of its dispenser, will necessarily result in wastage of the product?

K. Did Defendants' packaging of eye drops in bottles that dispensed drops of a size that was larger than the capacity of the eye cause consumers substantial injury as a result of paying for more medication than they needed and undergoing a risk of adverse health consequences?

L. Was the injury sustained by consumers from Defendants' packaging of eye drops in bottles that dispensed drops of a size that was larger than the capacity of the eye outweighed by countervailing benefits to consumers or to competition?

M. Was the injury sustained by consumers from Defendants' packaging of eye drops in bottles that dispensed drops of a size that was larger than the capacity of the eye reasonably avoidable by consumers who used those products?

N. Are the damages sustained by Class Members measured by what they paid for the portion of eye drops in excess of 15 μL.

O. Will declaratory and injunctive relief prevent harm caused to members of the Classes going forward?

P. Did Defendants' act with the malice necessary for the imposition of punitive damages?

Q. Should Defendants' be required to pay Plaintiffs' attorneys' fees?

R. Were Defendants unjustly enriched by receiving monies from the plaintiffs and Class Members for prescription eye medication that the plaintiffs were unable to use due to the Defendants' packaging?

S. Is it fair and equitable to permit the Defendants to retain the monies received from the plaintiffs and Class Members for prescription eye medication that the plaintiffs were unable to use due to the Defendants' packaging?

158. **Typicality.** Pursuant to Rule 23(a)(3), the claims of Plaintiffs are typical of the claims of the members of their respective Classes.

159. **Adequacy of Representation.** Moreover, as required by Rule 23(a)(4), Plaintiffs are adequate representatives of their respective Classes and have no conflict of interest with other Class Members. Plaintiffs' counsel are experienced in this type of litigation and will prosecute the action adequately and vigorously on behalf of the Classes.

160. **Rule 23(b)(2) elements.** Certification of the Classes is proper under Rule 23(b)(2) because Defendants have acted on grounds that apply generally to the Classes so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Classes as a whole.

161. **Predominance.** Certification of the Classes is proper under Rule 23(b)(3) since questions of law or fact common to each of the Classes predominate over any questions affecting only individual Class Members. The central issue in this case is common among all Class Members: whether Defendants' practice of selling prescription eye drops in containers that emit drops in excess of 15 μL violates the Massachusetts Consumer Protection Act and the comparable consumer protection statutes of Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia California, and whether, consistent with common law equitable principles, the Defendants have been unjustly enriched by this practice and should be allowed to retain the money had and received from the Plaintiffs and

the Classes, because the practice compels all Class Members to pay for product that will be necessarily wasted. These questions predominate over any possible questions affecting only individual Class Members.

162. **Superiority.** Further, certification of the Classes is similarly proper under Rule 23(b)(3) since a class action is superior to other available methods for fairly and efficiently adjudicating the controversy because, among other reasons, such treatment will permit a large number of similarly situated persons and entities to prosecute their claims simultaneously and efficiently without the unnecessary duplication of evidence, effort and expense that numerous individual cases would engender. In addition, the class action mechanism is the only method by which Class Members with small claims could, as a practical matter, seek redress for the wrongs committed by Defendants. The benefits of class action treatment substantially outweigh the difficulties, if any, that may arise in the management of this case as a class action. There are no unusual difficulties that might arise in the management of this case as a class action.

163. Certification of the Classes for purposes of pursuing injunctive relief is proper under Rule 23(b)(2) because Defendants' conduct has affected all members of the Classes in the same manner, and, in the absence of injunctive relief, will continue to do so. Class Members have no adequate remedy at law to redress the wrongs which are committed by Defendants on a continuing basis.

DEFENDANTS' ACTIONS ARE UNFAIR UNDER THE FTC'S INTERPRETATION OF SECTION 5(a) OF THE FTC ACT

164. As described more fully below, the consumer protection statutes of Massachusetts and the other states encompassed by this lawsuit incorporate the Federal Trade Commission's interpretations of § 5(a) of the Federal Trade Commission ("FTC") Act in their prohibitions,

either by statute or case law. Section 5(a) of the FTC Act declares unlawful "[u]nfair or deceptive acts or practices in or affecting commerce."

165. Since the 1980s, the FTC has followed its Unfairness Policy Statement, which defines unfairness under the FTC Act in terms of three elements. Under this standard, "[a]n act or practice is 'unfair' under Section 5 if it 'causes or is likely to cause [1] substantial injury to consumers [2] which is not reasonably avoidable by consumers themselves and [3] not outweighed by countervailing benefits to consumers or to competition.'"[81]

166. As described in this Complaint, the consumer injury caused by Defendants' practices of selling topical ophthalmic prescription medication in dispensers that emit excessively large drops satisfies each of the elements necessary to establish an unfair practice.

167. First, Defendants' practices cause substantial consumer injury for two reasons. As the FTC's Unfairness Policy Statement states, "[i]n most cases a substantial injury involves monetary harm, as when sellers coerce consumers into purchasing unwanted goods or services …."[82] That is precisely what Defendants have done by compelling consumers into purchasing unwanted amounts of prescription eye drops.

[81] The Structure and Practices of the Debt Buying Industry, 2013 WL 419348 (F.T.C. January 1, 2013) at *8, quoting 15 U.S.C. § 45(n) (codifying the Commission's unfairness analysis); *see also* Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, United States Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (December 17, 1980), reprinted in the Appendix to *In the Matter of Int'l Harvester Co.*, 104 F.T.C. 949, 1079, 1074 n.3 (1984) (hereafter "FTC Unfairness Policy Statement") and also available on the FTC's web site at http://www.ftc.gov/bcp/policystmt/ad-unfair.htm. The FTC and the courts call this letter its "Unfairness Policy Statement" or "Policy Statement on Unfairness." *See id.*; Debt Buying Industry, 2013 WL 419348 (F.T.C.) at *8, n. 19; Am. Fin. *Servs. Ass'n v. F.T.C.*, 767 F.2d 957, 970-71 (D.C. Cir. 1985); *F.T.C. v. Cantkier*, 767 F. Supp. 2d 147, 153 (D.D.C. 2011); *F.T.C. v. Accusearch, Inc.*, 06-CV-105-D, 2007 WL 4356786 at *7 (D. Wyo. Sept. 28, 2007), *aff'd*, 570 F.3d 1187 (10th Cir. 2009); *see also Orkin Exterminating Co., Inc. v. F.T.C.*, 849 F.2d 1354, 1364 n. 10 (11th Cir. 1988) (referring to the letter as "the FTC's 'Policy Statement' on the meaning of unfair acts and practices").

[82] FTC Unfairness Policy Statement.

168. Furthermore, the FTC states: "An injury may be sufficiently substantial … if it does a small harm to a large number of people …."[83] As shown herein, the harm caused by excessively large eye drops affects millions of consumers who use prescription eye drops.

169. In addition, the FTC Policy Statement states: "Unwarranted health and safety risks may also support a finding of unfairness." As described herein, the large sizes of Defendants' prescription eye drops cause unwarranted health and safety risks in the following ways.

170. First, because the drops are larger than the capacity of the eye to absorb, substantial portions pass through the lacrimal or tear duct and enter the bloodstream without first being metabolically inactivated in the liver. As a result, patients are placed at an unwarranted risk of systemic toxic side effects, such as bronchospasm, palpitation, reduced blood pressure, slowed heart rate, syncope, exercise intolerance, depression, anxiety, disorientation, confusion, headaches, fatigue, drowsiness, dry mouth and hypertension. The elderly are at increased risk of at least some of these effects compared to younger individuals.

171. In addition, the excessive size of prostaglandins such as Alcon's Travatan Z, Allergan's Lumigan and Pfizer's Xalatan increases the risk of local side effects such as lengthening, thickening and hyperpigmentation of eyelashes, darkening of the iris, and hyperpigmentation of the skin around the eye.

172. Moreover, the size of Defendants' eye drops contributes to a situation where many patients with glaucoma run out of their medication before their insurer or other third-party payor will reimburse them for a replacement bottle. Because these drugs are so expensive, many

[83] *In the Matter of Int'l Harvester Co*., 104 F.T.C. 949, n. 12 (1984).

patients cannot afford to buy them on their own and therefore go without, placing them at increased risk of loss of vision or complete blindness.

173. Defendants' practices also meet the second element of the FTC's Unfairness Policy Statement of not being reasonably avoidable by consumers themselves. As described herein, there are several reasons for this.

174. First, individual patients do not choose which drugs to take; they are prescribed their drugs by their physicians. Once the doctor has prescribed a prescription eye drop, the patient has no alternative other than rejecting the physician's advice and foregoing the treatment entirely.

175. Moreover, consumers cannot avoid product wastage by switching to an alternative product, because all prescription eye drops are substantially larger than 15 μL and therefore lead to wastage.

176. In addition, it is impossible to instill less than one eye drop into one's eye. Thus, a consumer must consume the entirety of the excessively large drop supplied by the manufacturer, even though only a portion provides any benefit.

177. Finally, Defendants' practices meet the third and final element of the FTC's Unfairness Policy Statement in that the consumers' injuries are not outweighed by countervailing benefits to consumers or competition. In fact, there are no countervailing benefits to consumers or competition from the excessively large eye drops that Defendants sell.

VIOLATIONS OF MASSACHUSETTS CONSUMER PROTECTION ACT AND SIMILAR STATUTES OF OTHER STATES

178. Massachusetts prohibits "[u]nfair or deceptive acts or practices in the conduct of any trade or commerce …." M.G.L. c. 93A § 2.

179. In outlawing unfair acts or practices, the Massachusetts Legislature adopted the FTC's interpretations of § 5(a)(1) of the Federal Trade Commission Act. M.G.L. c. 93A § 2(b).

180. A person who has suffered a loss as a result of a violation of the Massachusetts Consumer Protection Act may recover actual damages, double or treble damages, plus attorney's fees and court costs.

181. Defendants violated the Massachusetts Consumer Protection Act by selling prescription eye drop medications in dispensers that emit drops that are so large that they exceed the capacity of the eye, with large portions being expelled from the eye and providing no pharmaceutical benefit and a risk of harm, causing patients, including the Massachusetts Plaintiffs and Class Members, to spend substantial sums of money on medication that is unwanted and unneeded.

182. Defendants' actions, as alleged herein, were performed intentionally, willfully, knowingly, and maliciously.

183. The following states have consumer protection statutes that, like those of Massachusetts, prohibit unfair or unconscionable practices:

Arkansas: ARK. CODE ANN. § 4-88-107, et seq.

Connecticut: CONN. GEN. STAT. § 42-110b, et seq.

Hawaii: HAW. REV. STAT. § 480, et seq.

Idaho: IDAHO CODE § 48-601, et seq.

Kansas: KAN. STAT. § 50-623, et seq.

Maine: ME. REV. STAT. Tit. 5, § 205-A, et seq.

Maryland: MD. CODE. ANN., COM. LAW § 13-101, et seq.

Nebraska: NEB. REV. STAT. § 59-1601, et seq.

New Hampshire: N.H. REV. STAT. ANN. § 358-A:1, et seq.

New Mexico: N.M. STAT. ANN. § 57-12-1, et seq.

Oklahoma: OKLA. STAT. Tit. 15, § 751, et seq.

Oregon: OR. REV. STAT. § 646.605, et seq.

Rhode Island: R.I. GEN. LAWS § 6-13.1-1, et seq.

Vermont: VT. STAT. ANN. Tit. 9, § 2451, et seq.

Washington: WASH. REV. CODE § 19.86.010, et seq.

West Virginia: W. VA. CODE § 46A-6-101, et seq.

Wyoming: WYO. STAT. ANN. § 40-12-101, et seq.

184. The following states' statutes are among those that broadly prohibit unfair acts and practices: Connecticut, Hawaii, Maine, Maryland, Nebraska, New Hampshire, Oklahoma, Rhode Island, Vermont, Washington, West Virginia, and Wyoming.

185. The states of Arkansas, Idaho, Kansas, and New Mexico prohibit "unconscionable" conduct.

186. Oregon also outlaws "unfair or deceptive conduct in trade or commerce," as well as "any unconscionable tactic in connection with the sale, rental or other disposition of real estate, goods or services." Or. Rev. Stat. § 646.607(1) and 646.608(u).

187. In addition to Massachusetts, the following states, by statute, state regulation or case law, expressly incorporate the FTC's and the courts' interpretations of Section 5 of the FTC Act into their consumer protection statutes: Connecticut, Hawaii, Idaho, Maine, Maryland, Massachusetts, New Hampshire, Rhode Island, Texas, Washington, and West Virginia.

188. The statutes of each of these states provide consumers and/or other end payors with a private right of action for the unfair and/or unconscionable acts and practices of Defendants.

COUNT I: VIOLATION OF STATE CONSUMER PROTECTION STATUTES

189. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

190. This count is brought on behalf of the Alcon UDAP Sub-Class, Allergan UDAP Sub-Class, Pfizer UDAP Sub-Class, Valeant UDAP Sub-Class, Merck UDAP Sub-Class, Prasco UDAP Sub-Class, and Akorn UDAP Sub-Class, pursuant to Massachusetts General Law c. 93A and similar or identical consumer protection and consumer fraud statutes in Arkansas, Connecticut, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia by Plaintiffs, individually, and on behalf all others similarly situated against Defendants.

191. The Defendants are engaged in trade and commerce.

192. Defendants have engaged in unfair acts and practices as described above and by selling prescription eye drop medications in dispensers that emit drops that are so large that they exceed the capacity of the eye, with large portions of the medications expelled from the eye and providing no pharmaceutical benefit and a risk of harm.

193. These unfair acts and practices have been made unlawful under Massachusetts General Law c. 93A and similar or identical consumer protection and consumer fraud statutes in the other states set forth above.

194. Defendants have engaged in the unfair acts and practices as described above willfully and knowingly.

195. Plaintiffs have provided pre-suit notices and demands as required by M.G.L. c. 93A and any other applicable pre-suit notice or demand requirements set forth in the consumer protection and consumer fraud laws in the states set forth above.

196. Defendants have engaged in unfair acts or practices in violation of Arkansas Code §4-88-101 et. seq.

197. Defendants have engaged in unfair acts or practices in violation of Connecticut Gen. Stat. §42.110b, et. seq.

198. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of District of Columbia Code §28-3901, et. seq.

199. Defendants have engaged in unfair acts or practices in violation of Hawaii Rev. Stat. §480, et. seq.

200. Defendants have engaged in unfair acts or practices in violation of Idaho Code §48-601 et. seq.

201. Defendants have engaged in unfair acts or practices in violation of Indiana Code Ann. §24-5-0-5.1., et. seq.

202. Defendants have engaged in unfair acts or practices in violation of Kansas Stat. §50-623, et. seq.

203. Defendants have engaged in unfair acts or practices in violation of Kentucky Rev. Stat. §367.110 et. seq.

204. Defendants have engaged in unfair acts or practices in violation of Maine Rev. Stat. Tit. 5, § 205-A, et seq.

205. Defendants have engaged in unfair acts or practices in violation of Maryland Com. Law Code §13-101, et. seq.

206. Defendants have engaged in unfair acts or practices in violation of Massachusetts Gen. L. Ch. 93A, et. seq.

207. Defendants have engaged in unfair acts or practices in violation of Michigan Stat. §445.901, et. seq.

208. Defendants have engaged in unfair acts or practices in violation of Montana Code §30-14-101, et. seq.

209. Defendants have engaged in unfair acts or practices in violation of Nebraska Rev. Stat. §59-1601, et. seq.

210. Defendants have engaged in unfair acts or practices in violation of New Hampshire Rev. Stat. §358-A:1, et. seq.

211. Defendants have engaged in unfair acts or practices in violation of New Mexico Stat. §57-12-1, et. seq.

212. Defendants have engaged in unfair acts or practices in violation of Ohio Rev. Stat. §1345.01, et. seq.

213. Defendants have engaged in unfair acts or practices in violation of Oklahoma Stat. Tit. 15, §751, et. seq.

214. Defendants have engaged in unfair acts or practices in violation of Oregon Rev. Stat. §646.605 et. seq.

215. Defendants have engaged in unfair acts or practices in violation of 73 Pennsylvania Stat. §201-1, et. seq.

216. Defendants have engaged in unfair acts or practices in violation of Rhode Island Gen. Laws §6-13.1-1, et. seq.

217. Defendants have engaged in unfair acts or practices in violation of South Carolina Code Laws §39-5-10, et. seq.

218. Defendants have engaged in unfair acts or practices in violation of Utah Code §13.11-1, et. seq.

219. Defendants have engaged in unfair acts or practices in violation of 9 Vermont §2451, et. seq.

220. Defendants have engaged in unfair acts or practices in violation of Washington Rev. Code §19.86.010, et. seq.

221. Defendants have engaged in unfair acts or practices in violation of West Virginia Code §46A-6-101, et seq.

222. Defendants have engaged in unfair acts or practices in violation of Wyoming Stat. Ann. § 40-12-101, et seq.

223. The Defendants' unfair and deceptive acts and practices have directly, foreseeably, and proximately caused or will cause damages and injury to Plaintiffs and the members of the Alcon UDAP Sub-Class, Allergan UDAP Sub-Class, Pfizer UDAP Sub-Class, Valeant UDAP Sub-Class, Merck UDAP Sub-Class, Prasco UDAP Sub-Class, and Akorn UDAP Sub-Class.

224. Plaintiffs and the members of the Alcon UDAP Sub-Class, Allergan UDAP Sub-Class, Pfizer UDAP Sub-Class, Valeant UDAP Sub-Class, Merck UDAP Sub-Class, Prasco

UDAP Sub-Class, and Akorn UDAP Sub-Class and all others similarly situated were injured and sustained ascertainable losses and damages in amounts to be proven at trial, as a direct and proximate result of Defendants' unfair and deceptive acts and practices because, among other things, they had to purchase medication that was unwanted and unneeded.

225. By reason of the foregoing, Plaintiffs and the members of the Alcon UDAP Sub-Class, Allergan UDAP Sub-Class, Pfizer UDAP Sub-Class, Valeant UDAP Sub-Class, Merck UDAP Sub-Class, Prasco UDAP Sub-Class, and Akorn UDAP Sub-Class and all others similarly situated are entitled to receive their actual damages, or statutory damages as applicable. Because Defendants acted willfully or knowingly, the Plaintiffs and the members of the Alcon UDAP Sub-Class, Allergan UDAP Sub-Class, Pfizer UDAP Sub-Class, Valeant UDAP Sub-Class, Merck UDAP Sub-Class, Prasco UDAP Sub-Class, and Akorn UDAP Sub-Class and all others similarly situated are entitled to recover up to three times their actual damages, or additional punitive or exemplary damages and attorneys' fees as applicable under the consumer protection and consumer fraud statutes set forth below.

COUNT II: UNJUST ENRICHMENT

226. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

227. This count is brought on behalf of the Alcon Common Law Sub-Class, Allergan Common Law Sub-Class, Pfizer Common Law Sub-Class, Valeant Common Law Sub-Class, Merck Common Law Sub-Class, Prasco Common Law Sub-Class, and Akorn Sub-Class to obtain unjust enrichment remedies pursuant to the laws of Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin.

228. As is more fully set forth above, Defendants engaged in unfair and deceptive acts or practices in connection with their packaging and sale of prescription eye medication.

229. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefitted from payments made by the Plaintiffs and those similarly situated for the purchase of Defendants' products.

230. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and those similarly situated have purchased more of the Defendants' product than was pharmaceutically necessary or could be used to treat their medical conditions and were forced to waste medication due to the manner in which the medication was packaged and delivered for use.

231. As a direct result of this conduct and the payments received for the products sold, Defendants have been unjustly enriched.

232. Plaintiffs and those similarly situated are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount, deemed appropriate by the Court to remedy Defendants' unjust enrichment, and such other relief as the Court deems just and proper.

COUNT III: MONEY HAD AND RECEIVED

233. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

234. This count is brought on behalf of the Alcon Common Law Sub-Class, Allergan Common Law Sub-Class, Pfizer Common Law Sub-Class, Valeant Common Law Sub-Class, Merck Common Law Sub-Class, Prasco Common Law Sub-Class, and Akorn Sub-Class to obtain remedies due to Defendants unfair and inequitable retention of money had and received from the Plaintiffs and the members of the Common Law Subclasses pursuant to the laws of

Alabama, Alaska, Arizona, Colorado, Delaware, Georgia, Iowa, Louisiana, Minnesota, Mississippi, Nevada, New York, North Dakota, South Dakota, Tennessee, Virginia and Wisconsin.

235. As is more fully set forth above, Defendants engaged in unfair and deceptive acts or practices in connection with their packaging and sale of prescription eye medication.

236. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants received payments from the Plaintiffs and those similarly situated for the purchase of Defendants' products.

237. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and those similarly situated have purchased more of the Defendants' product than was pharmaceutically necessary or could be used to treat their medical conditions and were forced to waste medication due to the manner in which the medication was packaged and delivered for use.

238. The money had and received by the Defendants from the purchase of the products that are the subject of this action should not in justice be retained by the defendant, and should, in equity and good conscience be returned or paid back to the Plaintiffs and those similarly situated.

239. Plaintiffs and those similarly situated are entitled in equity to seek restitution of Defendants' money had and received, to the extent and in the amount, deemed equitable and appropriate by the Court to remedy Defendants' unjust retention of the proceeds of any applicable sales, and such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Classes, pray judgment against Defendants as follows:

1. Certifying the Classes and Subclasses as requested herein;
2. Entering an order appointing DeMoura|Smith LLP and Perini-Hegarty & Associates, P.C., as lead counsel for the Classes;
3. Awarding actual damages from each Defendant in an amount that together exceeds the aggregate sum of $5,000,000 to Plaintiffs and the members of the Classes and Subclasses;
4. Awarding punitive damages against each Defendant as the court deems necessary or proper;
5. Awarding exemplary, double or treble damages as permitted by statute;
6. Awarding declaratory and injunctive relief as permitted by law or equity including a preliminary and permanent injunction enjoining Defendants from continuing the unlawful practices as set forth herein;
7. Awarding pre-judgment and post-judgment interest;
8. Awarding reasonable attorneys' fees and costs herein;
9. Awarding such other and further relief as the court deems fit and proper.

Respectfully submitted,

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Appendix
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